

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Protocol summary

Study aim

Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Design

In this double-blind clinical trial study (participants and results analyzer), patients will undergo surgery after random allocation in the two mentioned groups. For one group, the routine procedure will be performed and for the other group, Hook's circulators will be performed minimally invasively, and the results after surgery will be compared between the two groups.

Settings and conduct

This study is a randomized clinical trial (blocks of four), double blind (participants and results analyzer), with parallel groups, without a control group and with the participation of 80 patients with pilonidal sinus surgery referred to Imam Reza Hospital (Tabriz).

Participants/Inclusion and exclusion criteria

The inclusion criteria include: age over 18 years, consent to participate in the study and suffering from pilonidal sinus will be determined by the doctor, and the exclusion criteria will also include: history of uncontrolled blood pressure and recurrent pilonidal sinus.

Intervention groups

In this study, patients who will refer to the operating room due to pilonidal sinus surgery will undergo intervention. Patients will be randomly divided into two groups. For one group, the routine procedure will be performed and for the other group, Hook's circulators will be performed minimally invasively, and the results after surgery will be compared between the two groups.

Main outcome variables

Infection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N43**

Registration date: **2024-02-10, 1402/11/21**

Registration timing: **prospective**

Last update: **2024-02-10, 1402/11/21**

Update count: **0**

Registration date

2024-02-10, 1402/11/21

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-14, 1402/12/24

Expected recruitment end date

2025-03-14, 1403/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Public title

Comparing the results of pilonidal sinus surgery under video guide with minimally invasive hook circulators with routine method

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age above 18 years
Consent to participate in the study
Having pilonidal sinus as diagnosed by a specialist doctor

Exclusion criteria:

History of uncontrolled blood pressure
Recurrent pilonidal sinus

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1: BBAA, block 2: AABB, block 3: ABAB, block 4: BABA, block 5: ABBA, and block 6: BAAB, we need 20 blocks for 80 people. It is random in the block method. We choose numbers from one to six. For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right. and finally they will divide into two intervention groups (group A) and control group (group B).

Blinding (investigator's opinion)

Double blinded

Blinding description

The thesis results analyst who will analyze the expected result and also the participants will be unaware of the type of procedure performed and will be blind during the study; Therefore, this study will be conducted in a double-blind manner. Since the participants will be unaware of the type of technique used, in this study they will not know what type of technique will be used in other patients.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Approval date

2023-12-17, 1402/09/26

Ethics committee reference number

IR.TBZMED.REC.1402.708

Health conditions studied

1

Description of health condition studied

Infection

ICD-10 code

A04

ICD-10 code description

Other bacterial intestinal infections

Primary outcomes

1

Description

Infection

Timepoint

Once a week in the first thirty days after surgery

Method of measurement

Physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The surgical procedure will be as follows: using hook circulators under the video guide, the pitting area of the pilonidal sinus is removed in a circular manner and entered into the sinus cavity, then electrical curettage is performed using hook circulators instead of mechanical curettage. Finally, the infection rate will be

measured.
Category
Treatment - Devices

2

Description

Control group: The surgical procedure will be as follows, without using hook circulators, under the video guide, the pitting area of the pilonidal sinus is removed in a circular manner and entered into the sinus cavity, then electrical curettage is performed using hook circulators instead of mechanical curettage. Finally, the infection rate will be measured.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Ramin Azhoogh
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mehdi Khanbabayi Gol
Position
MSc in Nursing Education
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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable